

Sterile U Network

TUTORIALS

Understanding the Differences Between Class 5 Chemical Integrators and Class 6 Emulating Indicators

Background:

In December, 2005 the International Organization for Standardization (ISO) published a new document, ISO 11140-1: 2005 *Sterilization of healthcare products – Chemical Indicators – Part 1: general requirements*. The AAMI organization has approved this standard *without* US deviations, which means this document is now a recognized AAMI Standard.

There are two key changes you should be aware of:

1. Class 5 Integrating Indicator requirements were upgraded.
2. Class 6 Emulating Indicators, which were already part of an earlier ISO standard, are now included in the AAMI Standard.¹

The remainder of this tutorial will discuss the differences between Class 5 Integrating Indicators and Class 6 Emulating Indicators. By understanding these differences, Sterile Processing professionals can make informed decisions about which Chemical Indicator (CI) monitoring devices will provide the most accurate information regarding the sterilization conditions achieved inside a particular pack or load.

Key Definitions:

Understanding the key Chemical Indicator terms is critical in understanding the differences in Class 5 Integrating Indicators and Class 6 Emulating Indicators.

- **Critical variable:** “parameters identified as being essential to the sterilization process (and requiring monitoring).”¹



- **Endpoint:** “point of the observed change as defined by the manufacturer occurring after the indicator has been exposed to specified stated values.”¹ For example, the endpoint for a successful cycle for a moving-front style chemical indicator would be the color bar moving into the “accept” area (see Figure 1).

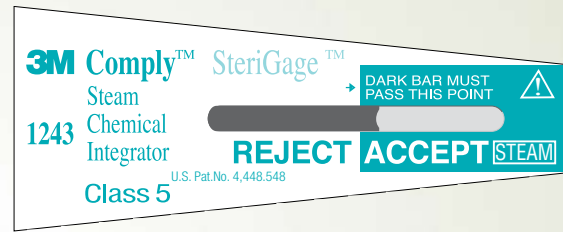


Figure 1: Illustration of endpoints moving-front style chemical indicators
Source: 3M internal data

- **Resistometer:** a specialized test vessel capable of reproducible cycles and used by Manufacturers to characterize the performance of chemical indicators.
- **Stated value (SV):** “value or values of a critical variable at which the indicator is designed to reach its endpoint as defined by the manufacturer.”¹ For example, a Class 5 Integrating Indicator with a stated value of 3.5 minutes at 134°C should reach its endpoint when tested at 134°C for 3.5 minutes in a resistometer (standardized test vessel).
- **Come-Up Time:** The time it takes for the sterilizer to achieve the selected exposure temperature.

Frequently Asked Questions:

1. Does the Class number have any significance? For example, is a Class 5 CI better than a Class 4, and is a Class 6 CI better than a Class 5?

Today, there are six classes of Chemical Indicators. The current ISO document classifies chemical indicators by their intended use and these classifications have no hierarchical significance.¹ For example the Bowie Dick Test is a Class 2 Chemical Indicator and probably provides more information about the steam sterilizer performance than any other class of chemical indicators. ISO provides performance requirements for each classification.

2. Are Class 5 and Class 6 CIs designed differently and how do those differences affect my monitoring processes?

This design differences are outlined in the table on the following page:



Design of Class 5 Chemical Integrators	Design of Class 6 Emulating Indicators	How does this affect my monitoring processes?
<p>Class 5 Integrating indicators are designed to react to all critical variables (time, temperature, and the presence of steam) <i>and</i> have Stated Values that correlate to a biological indicator (BI) at three time/temperature relationships.¹</p>	<p>Class 6 Emulating indicators are designed to react to all critical variables (time, temperature, and the presence of steam) for a <u>specified</u> sterilization cycle.¹ You may hear Class 6 indicators referred to as <i>cycle specific</i> indicators.</p>	<p>If your Sterile Processing Department runs multiple exposure times (e.g. 4, 10 and 18 minutes at 272°F), a distinct Class 6 emulating indicator would be required to monitor each cycle.</p>
<p>Class 5 Integrating indicators must have three Stated Values at 121°C, 135°C, and at one temperature in between that correlate to a BI.¹ Additionally, the Stated Value at 121°C must not be less than 16.5 minutes. This guarantees the time/temperature response for a Class 5 Integrating Indicator will respond like the BI when exposed to ideal, saturated steam (see Figure 2). Therefore, if the exposure temperature was not achieved where the Class 5 CI is located and the BI result was positive (a sterilization failure), the Class 5 CI will respond like the BI performance (thermal death rate curve of <i>G. stearothermophilus</i>) and also indicate that a failure had occurred.</p>	<p>Class 6 Emulating indicators have one Stated Value for time and temperature for the specific cycle it is designed for.¹</p> <p>There is no requirement for three Stated Values for time and temperature and therefore the response may not correlate to a BI. (see Figure 3)</p> <p>Note that at lower temperatures the Class 6 response can fall below that of the BI performance (thermal death rate curve of <i>G. stearothermophilus</i>).</p> <p>(see Figure 3)</p>	<p>Because the Class 5 Integrating Indicator response at lower temperatures parallels the biological response, Class 5 CIs are able to detect the failure condition where the desired exposure temperature is not achieved. This condition is likely to occur when there is:</p> <ul style="list-style-type: none"> • incorrect packaging • incorrect loading • air/steam mixtures • an incorrect cycle for load contents. <p>Because the Class 6 response at lower temperatures can fall below the thermal death curve of <i>G. stearothermophilus</i>, the Class 6 Emulating Indicator can reveal a pass when the BI would indicate a failure.</p>

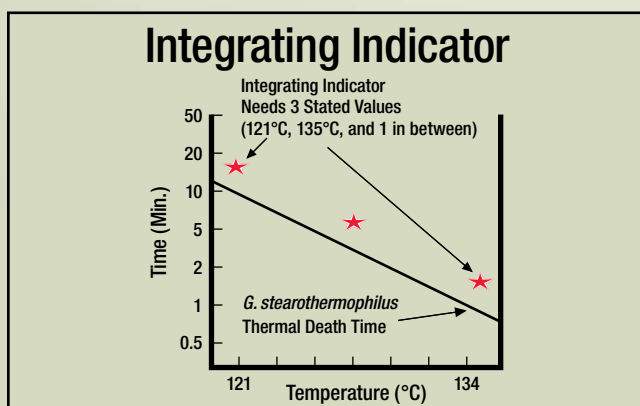


Figure 2: Time/Temperature Response for Class 5 Integrating Indicator Compared to Biological Indicator Response

Source: 3M internal test result

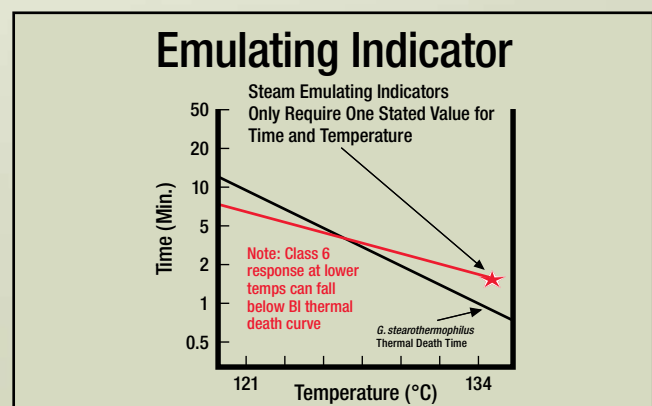


Figure 3: Time/Temperature Response for Class 6 Emulating Indicator Compared to Biological Indicator Response

Source: 3M internal test result



3. Has 3M completed performance testing of Class 5 CIs and Class 6 CIs in failure conditions?

Yes. 3M has tested its Class 5 Integrating indicator and two different Class 6 Emulating Indicators in several different steam sterilization conditions. The data from these studies was used to generate the graphs in Figures 2 and 3 above. The tests were done in a steam resistometer, the special test vessel that generates ideal saturated steam and is the vessel required for ANSI/AAMI/ISO Compliance Testing. What this testing revealed is that the 3M Class 5 Integrating Indicators do, in fact, correlate to the biological response or thermal death rate curve of *G. stearotherophilus*. Even though the Stated Values of the Class 6 Emulating Indicators were 3.5 minutes at 134°C, their time/temperature response compared to the biological response was faster at lower temperatures.

This 3M study also included testing 15 of each type of Class 5 and Class 6 indicator in a shortened, hospital type cycle (see Figure 4).

All the Class 6 products gave a PASS result which means they failed to detect the shortened exposure time even though their Stated Values at 134°C were greater than that of the Class 5 product. This data shows that the Class 6 products responded during the come-up time and progressed to their endpoint too soon to detect the steam sterilization process failure that occurred as a result of not reaching the exposure temperatures.

Hospital-Type Gravity Steam Cycle: 1-Minute Exposure at 134°C; 4-Minute Come-up Time	
<u>Indicator Type</u>	<u># Showing FAIL/ # Tested</u>
Class 5 (SV: 2.2 Min. @ 134°C)	15/15
Class 6 (SV: 3.5 Min. @ 134°C)	0/15
Class 6 (SV: 3.5 Min. @ 134°C)	0/15

Figure 4: Class 5 vs Class 6 CI Results in a Failure Condition
Source: 3M internal test result

4. Why are resistometers used for testing chemical and biological indicators?

Resistometers are specialized vessels that can create reproducible test cycles. They were chosen by the Standard Committees so manufacturers utilize common reproducible cycles to verify CI and BI performance. There are hundreds of possible hospital cycles where the depth of vacuum, the number of steam/vacuum pulses, the sterilizer come-up time, and the steam quality differ. These differences would make it impossible to provide consistent CI performance results for hospitals.

Steam resistometers must reach the desired temperature in < 10 seconds (see Figure 5). Hospital sterilizers, however, may have up to 10 minutes of pre-conditioning or come-up time (see Figure 6). BI inactivation and CI progression toward endpoint begins to occur during this pre-conditioning or come-up time in hospital sterilizers.



5. So what does this mean in a hospital sterilizer?

The cycle specific data for Class 6 Emulating Indicators *is generated in a resistometer* as well, not in a hospital sterilizer. Therefore, in a hospital sterilizer, Class 6 Emulating Indicators could have significant progression toward their endpoint during the come-up time and reach their endpoint much sooner than their Stated Value time and temperature.

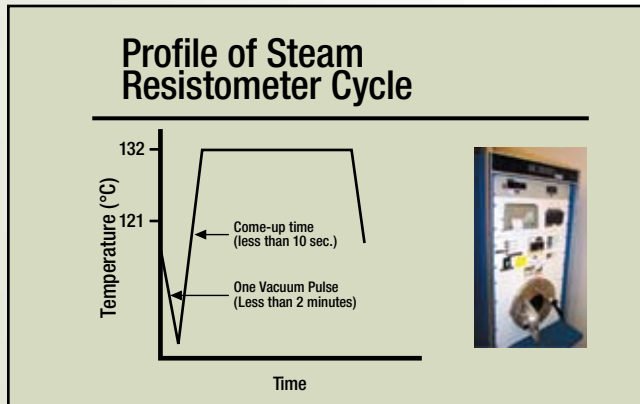


Figure 5: Resistometer Cycle Profile

Source: 3M internal data

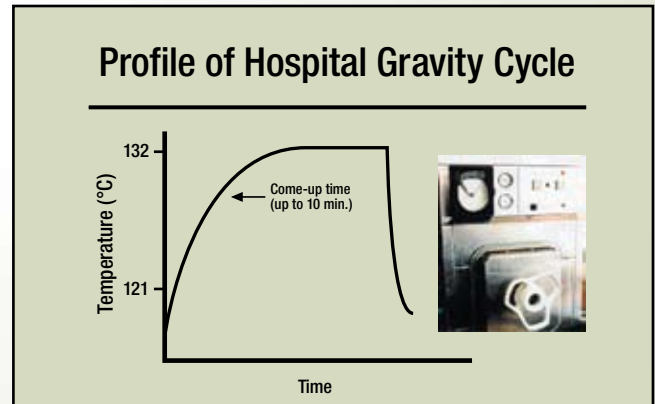


Figure 6: Hospital Cycle Profile

Source: 3M internal data

6. What does 3M recommend regarding the use of Class 5 and Class 6 CIs?

3M recommends the use of a Class 5 Integrating Indicator:

- inside a BI Process Challenge Device (PCD) as required by the AAMI ST79 for monitoring implant loads
- inside a PCD for monitoring loads when a BI PCD is not being run
- for internal pack monitoring
- a Class 6 Emulating Indicator could be used as an internal indicator at the pack/tray level in cycles for which it is labeled

This recommendation is based on the following:

- A Class 5 Integrating Indicator reacts to all critical variables *and* has **three** Stated Values that correlate to a BI at three time/temperature relationships (see Figure 1). This means a Class 5 integrating indicator will detect failure conditions where the selected exposure temperature is not achieved.



- The Class 5 Integrating Indicator Stated Value at 121°C must not be less than 16.5 minutes. A CI with a Stated Value at 121°C of less than 16.5 minutes can reach its endpoint too quickly at lower temperatures and miss a sterilization process failure.
- If a load is being released on the results of a Class 5 Integrating Indicator, it is critical the CI be able to show correct results at lower temperatures that is similar with BI performance (see Figure 1). Figure 2 shows how an Emulating Indicator might compare to BI performance in a Resistometer test vessel. Because Emulating Indicators only require one stated value for time and temperature, at lower temperatures the response of a Class 6 Emulating Indicator can fall below the BI thermal death curve.(see Figure 2)

For more information, call the 3M Help Line: 1-800-228-3957

¹ Association for the Advancement of Medical Instrumentation, *Sterilization of health care products-Chemical indicators-Part 1: General requirements*, ANSI/AAMI/ISO 11140-1:2005.



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3M Center, Building 275-4W-02
St. Paul, MN, 55144-1000
U.S.A.

www.3m.com

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